



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/591,852

07/24/2008

Walter Weyler

GC836-US

8235

5100 7590 12/22/2010
DANISCO US INC.
ATTENTION: LEGAL DEPARTMENT
925 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER

LEE, JAE W

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

12/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,852	Applicant(s) WEYLER ET AL.	
	Examiner JAE W. LEE	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-85 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application status

Claims 1-85 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-27, drawn to a microorganism comprising a modified pckA gene.

Group II, claims 28-37, drawn to an isolated nucleic acid comprising at least one sequence set forth in a nucleic acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:11, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:42, SEQ ID NO:44, SEQ ID NO:46, SEQ ID NO:48, SEQ ID NO:50, SEQ ID NO:37, SEQ ID NO:25, SEQ ID NO:21, SEQ ID NO:50, SEQ ID NO:23, SEQ ID NO:27, SEQ ID NO:19, SEQ ID NO:31, SEQ ID NO:48, SEQ ID NO:46, SEQ ID NO:35, and SEQ ID NO:33, a purified DNA construct comprising said nucleic acid, and a host cell transformed with said DNA construct.

Group III, claims 38-44 and 55-64, drawn to a method for enhancing production of at least one protein by a microorganism, comprising the steps: a) providing a microorganism host cell; b) inactivating the pckA gene in said host cell to produce an altered strain; and c) growing said altered strain under growth conditions suitable for expression of said protein.

Group IV, claims 45-54, drawn to a method for obtaining an altered Bacillus strain expressing a protein of interest, comprising the steps of transforming a Bacillus host cell with a DNA construct comprising an incoming sequence which comprises the pckA

Art Unit: 1656

gene, wherein said incoming sequence is integrated into the chromosome of said Bacillus host cell to produce an altered Bacillus strain, further in which one or more chromosomal genes have been inactivated; and growing said altered Bacillus strain under suitable growth conditions for the expression of a at least one protein of interest.

Group V, claims 65-74, drawn to a method for enhancing the expression of a protein of interest in Bacillus comprising: introducing a DNA construct including a selective marker and an inactivating chromosomal segment into a Bacillus host strain, wherein said DNA construct is integrated into the chromosome of the Bacillus host strain, resulting in the deletion of an indigenous chromosomal region or fragment thereof from said Bacillus host strain to produce an altered Bacillus strain; and growing said altered Bacillus strain under suitable conditions, wherein expression of a protein of interest is greater in said altered Bacillus strain compared to the expression of the protein of interest in said Bacillus host strain.

Group VI, claims 75-81, drawn to a method for enhancing the expression of a protein of interest in Bacillus comprising: obtaining nucleic acid from at least one Bacillus cell; performing transcriptome DNA array analysis on the nucleic acid from said Bacillus cell to identify at least one gene of interest; modifying said at least one gene of interest to produce a DNA construct; introducing said DNA construct into a Bacillus host cell to produce an altered Bacillus strain, wherein said altered Bacillus strain is capable of producing a protein of interest, under conditions such that expression of said protein of interest is enhanced as compared to the expression of the protein of interest in a Bacillus that has not been altered.

Group VII, claims 82-85, drawn to a method for enhancing the expression of a protein of interest in Bacillus, comprising: obtaining nucleic acid containing at least one gene of interest from at least one Bacillus cell; fragmenting said nucleic acid; amplifying said fragments to produce a pool of amplified fragments comprising said at least one gene of interest; ligating said amplified fragments to produce a DNA construct; directly transforming said DNA construct into a Bacillus host cell to produce an altered Bacillus strain, wherein said altered Bacillus strain comprises a modified gene selected from the group consisting of prpC, sigD and tdh/kbl; culturing said altered Bacillus strain under conditions such that expression of said protein of interest is enhanced as compared to the expression of said protein of interest in a Bacillus that has not been altered.

In addition to the above election, please elect a single nucleic acid SEQ ID NO and its corresponding amino acid SEQ ID NO as recited in Claims 28, 29, 33, 34, 53 and 54 (this is NOT a species election). These sequences are independent or distinct because these SEQ ID NOs represent structurally different nucleic acid/amino acid

Art Unit: 1656

sequences, and there is no shared special technical feature between these nucleic/amino acid sequences.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Ferrari et al. (WO/2003/083125) teach [1] a method for enhancing expression of a protein of interest from *Bacillus* comprising: a) obtaining an altered *Bacillus* strain capable of producing a protein of interest, wherein said altered *Bacillus* strain has at least one inactivated chromosomal gene selected from the group consisting of *sbo*, *sir*, *ybcO*, *csn*, *spolISA*, *sigB*, *phrC*, *rapA*, *CssS*, *trpA*, *trpB*, *trpC*, *trpD*, *trpE*, *trpF*, *tdh/kbl*, *alsD*, *sigD*, *prpC*, *gapB*, **pckA**, *fbp*, *rocA*, *ycgN*, *ycgM*, *rocF*, and *rocD*; and b) growing said altered *Bacillus* strain under conditions such that said protein of interest is expressed by said altered *Bacillus* strain, wherein said expression of said protein of interest is enhanced compared to the expression of said protein of interest in an unaltered *Bacillus* host strain (underlined for added emphasis), [2] said altered *Bacillus* strain, which corresponds to the limitation of claims 1, 3, 14 and 38, and thus,

Art Unit: 1656

the shared technical feature of the groups is not a “special technical feature”, unity of invention between the groups does not exist.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

Art Unit: 1656

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1656

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/

Examiner, Art Unit 1656

/SUZANNE M. NOAKES/

Primary Examiner, Art Unit 1656